

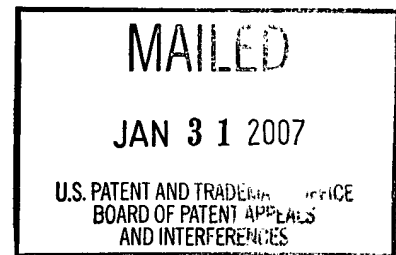
The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ROBERT T. HUDAK

Appeal 2006-2699
Application 09/915,494
Technology Center 1600



ON BRIEF

Before SCHEINER, GRIMES, and LINCK, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims to a specimen collection device. The Examiner has rejected the claims for anticipation or obviousness and provisionally rejected for obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 134. We affirm the provisional double patenting rejection, but reverse the anticipation and obviousness rejections.

BACKGROUND

The specification describes “a specimen collection device that includes a chamber . . . capable of collecting a specimen. The device also

includes a reservoir . . . capable of receiving a portion of the specimen from the chamber and optionally . . . capable of receiving a test device. The device optionally includes a valve functionally interposed between the chamber and the reservoir that is capable of transferring at least a portion of the specimen from the chamber to the reservoir.” (Specification 1.)

The valve “functions so as [to] acquire a measured portion of a specimen . . . collected in the chamber”; to “physically separate[] the measured portion of the specimen from the specimen remaining in the chamber”; and “to deliver and dispense the measured portion of the specimen into the reservoir.” (*Id.* at 17-18.) The specification describes embodiments in which “the means . . . for transferring a portion of the specimen in the valve . . . cannot be . . . actuated more than once.” (*Id.* at 20.)

DISCUSSION

1. CLAIMS

Claims 74-102 are on appeal. We will focus on claim 74, which is representative and reads as follows:

74. A specimen collection device, comprising:

- (a) a chamber for collecting a specimen;
- (b) a reservoir for receiving an aliquot of specimen from the chamber and for receiving a test device;
- (c) a valve functionally interposed between the chamber and the reservoir and having a compartment for holding an aliquot of specimen and transporting the aliquot from the chamber to the reservoir, the valve having first, second and third positions,

wherein

when the valve is in the first position, the valve compartment is in fluid communication with the chamber and is not in fluid communication with the reservoir;

when the valve is in the second position, the valve compartment is not in fluid communication with the chamber nor the reservoir;

when the valve is in the third position, the valve compartment is in fluid communication with the reservoir and is not in fluid communication with the chamber; and

the valve being inoperable after a first actuation.

Thus, claim 74 is directed to a specimen collection device comprising a specimen-collection chamber, a reservoir, and a valve having a compartment for transporting an aliquot of specimen from the chamber to the reservoir. The valve has a first position in which the valve compartment is in fluid communication with the chamber and not the reservoir, a second position in which the valve compartment is not in fluid communication with the chamber or the reservoir, and a third position in which the valve compartment is in fluid communication with the reservoir and not the chamber.

Claim 74 also states that the valve is “inoperable after a first actuation.” We interpret this limitation to mean that once the valve is moved from the first position to the second position, the valve becomes inoperable, such that it cannot transport a second aliquot of specimen from the chamber to the reservoir.

2. ANTICIPATION

Claims 74, 75, 79, 85-92, and 94-102 stand rejected under 35 U.S.C. § 102(e) as anticipated by Cui.¹ The Examiner states that Cui describes a device for collecting and testing a fluid specimen, the device having “a first compartment (chamber) for fluid collection”; “a second compartment (reservoir) for receiving a portion of the fluid”; and “a valve interposed between the first compartment and the second compartment (Fig. 1 and Fig. 9).” (Answer 3-4.) The Examiner argues that the “valve comprises a well (22) (compartment) for holding an aliquot of the specimen” and that “the second compartment (reservoir) is spaced to allow receipt of a test device such as a test strip (col 5).” (Answer 4.)

The Examiner also argues that, in Figure 2, Cui depicts a valve comprising “a well (valve compartment) in fluid communication with the chamber. One skilled in the art would recognize that when the valve is actuated that the well will be horizontal at the 3:00 . . . position (second position) (would not be in fluid communication with the chamber or the reservoir) and then proceed to the 6:00 . . . position in which the well (valve compartment) would be in fluid communication with the reservoir and not the chamber.” (*Id.*)

In addition, the Examiner states that the recitation “‘the valve being inoperable after a first actuation’ . . . is not given patentable weight because it is [the] intended use of the valve.” (*Id.*) The Examiner also argues that, because Cui discloses “structurally the same device and valve as recited in

¹ Cui, U.S. Patent No. 6,576,193 B1, issued June 10, 2003.

the instant claims, it is inherent that the device and valve would be capable of being inoperable after a first actuation.” (*Id.* at 10.)

Appellant argues that Cui does not disclose a device comprising a valve that is “inoperable after a first actuation.” (Br. 7. In particular, Appellant argues that “this limitation is not a mere recitation of intended use . . . , but represents a specific characteristic of the claimed invention and a genuine required limitation of the claim that must be evaluated with every other limitation – the claim requires that the valve be inoperable after a first actuation.” (Br. 7.)

We agree with Appellant that the recitation that the valve is “inoperable after a first actuation” is not merely a recitation of intended use. Instead, this recitation limits the valve to one having a structure that cannot transport a second aliquot of specimen from the chamber to the reservoir. In addition, we agree with Appellant that the Examiner has not set forth a *prima facie* case that Cui describes a device having such a valve. Thus, the Examiner has not demonstrated that Cui anticipates claim 74. We therefore reverse the § 102(e) rejection of claims 74, 75, 79, 85-92, and 94-102.

3. OBVIOUSNESS

Claims 76-78, 80-84, and 93 stand rejected under 35 U.S.C. § 103 as follows: claim 76 as obvious over Cui in view of Nelson,² claims 77 and 78 as obvious over Cui in view of Alley,³ claims 80 and 84 as obvious over Cui

² Nelson, U.S. Patent No. 5,115,934, issued May 26, 1992.

³ Alley, U.S. Patent Publication No. 2002/0046614 A1, published April 25, 2002.

in view of Mitsumaki⁴ and Pampinella,⁵ claims 81-83 as obvious over Cui in view of Carter,⁶ and claim 93 as obvious over Cui in view of Ehrenkranz.⁷

Claims 76-78, 80-84, and 93 depend from claim 74. We have already concluded that the Examiner has not set forth a prima facie case that Cui anticipates claim 74. In addition, the Examiner has not adequately shown that claim 74 would have been obvious over Cui. The Examiner relies on Nelson, Alley, Mitsumaki, Pampinella, Carter, and Ehrenkranz for limitations recited in dependent claims, and has not pointed to any disclosure in these references that would make up for the deficiencies discussed above. Thus, we conclude that the Examiner has not set forth a prima facie case that claims 76-78, 80-84, and 93 would have been obvious. We therefore reverse the obviousness rejections of these claims.

4. DOUBLE-PATENTING

The Examiner has provisionally rejected claims 74-102 under the judicially created doctrine of obviousness-type double patenting over claims 1-62 of U.S. Patent Application No. 10/211,199. Appellant does not traverse this rejection; therefore, we affirm it.

⁴ Mitsumaki, U.S. Patent No. 4,680,270, issued July 14, 1987.

⁵ Pampinella, U.S. Patent Publication No. 2002/0023482 A1, published February 28, 2002.

⁶ Carter, U.S. Patent No. 4,909,933, issued March 20, 1990.

⁷ Ehrenkranz, U.S. Patent No. 4,769,215, issued September 6, 1988.

SUMMARY

The Examiner has not adequately shown that the claims are anticipated or obvious over the applied prior art. We therefore reverse the anticipation and obviousness rejections. However, we affirm the provisional double patenting rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED



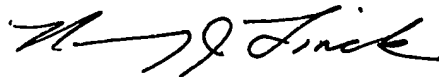
Toni R. Scheiner)
Administrative Patent Judge)



Eric Grimes)
Administrative Patent Judge)

) BOARD OF PATENT

) APPEALS AND



Nancy J. Linck)
Administrative Patent Judge)

) INTERFERENCES

EG/MLM/jlb

Appeal No. 2006-2699
Application No. 09/915,494

Fish & Richardson, P.C.
P.O. Box 1022
Minneapolis, MN 55440-1022